No. 22-13218

UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

VIRGINIA REDDING
Plaintiff/Appellee,

v.

COLOPLAST CORP.,
Defendants/Appellants.

Appeal from the Unites States District Court for the Middle District of Florida,
The Honorable Carlos E. Mendoza, District Judge
District Court Case No. 6:19-cv-01857-CEM-GJK

RESPONSE BRIEF OF APPELLEE VIRGINIA REDDING

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and 11th Circuit Local Rule 26.1-1, Plaintiff-Appellee Virginia Redding hereby files her certificate of interested persons and corporate disclosure statement:

1. Baker, Honorable David A. (United States Magistrate Judge for the Middle District of Florida)
2. Carlton Fields, P.A. (Counsel for Defendant/Appellant Coloplast Corp.)
3. Coloplast A/S (COLO-B, Nasdaq Copenhagen) (Parent corporation of Coloplast Corp.)
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16. Mendoza, Honorable Carlos E. (United States District Judge for the Middle District of Florida)
17. Moore, Geoffrey T. (Counsel for Plaintiff/Appellee Virginia Redding)
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19. Redding, Virginia (Plaintiff/Appellee)
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21. Wagstaff & Cartmell, LLP (Counsel for Plaintiff/Appellee Virginia Redding) (*admitted pro hac vice*)
22. Walz, David J. (Counsel for Defendant/Appellant Coloplast Corp.)

Plaintiff-Appellee Virginia Redding is not a corporation.

STATEMENT REGARDING ORAL ARGUMENT

Ms. Redding believes that the full Record supports the jury's decision and the district court's ruling, such that the Court could decide the case without oral argument. However, counsel for Ms. Redding will be happy to participate in oral argument if the Court believes it would be beneficial.

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STATEMENT AS TO JURISDICTION

Ms. Redding agrees with the jurisdictional statement in Coloplast's brief.

STATEMENT OF THE ISSUE

Whether a reasonable jury could find that Ms. Redding did not have a compensable claim against Coloplast, or had neither discovered nor had reason to discover such a claim, before September 28, 2010, given that no medical records or physician testimony indicate that Defendant's mesh products caused an injury to Ms. Redding before that date, and Ms. Redding's treating physician never told her that the mesh was causing any of her symptoms.

STATEMENT OF THE CASE

This case is a product liability action brought by Virginia Redding against Coloplast Corp. ("Coloplast") to recover for injuries suffered from 2014 through the present due to the implantation of two Coloplast synthetic mesh devices: the Supris sling, which treats stress urinary incontinence, and the Novasilk product, which treats pelvic organ prolapse.

I. Procedural History

Ms. Redding filed this case into the pelvic mesh MDL in the Southern District of West Virginia on September 18, 2014—only three months after the first of her two mesh revision surgeries. (Appellant App., Doc. A, at 5). The MDL court transferred the case to the Middle District of Florida for pretrial proceedings and trial on September 27, 2019. (*Id.* at 15). Coloplast moved for summary judgment on May 13, 2019, asserting that the statute of limitations barred Ms. Redding's claims, among other arguments. (Appellant App., Doc. 53, at 1-2). After remand, the trial court denied the motion, holding that the issue presented a question of fact under settled Eleventh Circuit interpretations of Florida law. (Appellant App., Doc. 110, at 7).

During trial, Coloplast filed a motion for judgment as a matter of law, again invoking the statute of limitations. (Appellant App., Doc. 360, at 2-11). Again, the court denied the motion. (Appellant App., Doc. 405, at 6-7). The jury's verdict

awarded Ms. Redding $2.5 million and specifically held that her claim had not accrued before September 28, 2010. (Verdict Form, Redding App., Doc. 397). The court then entered judgment on the jury's verdict. (Appellant App., Doc. 407). Undeterred, Coloplast raised the issue again in a renewed motion post-judgment. (Appellant App., Doc. 410, at 2-3). The court issued its third strike, denying Coloplast's motion once again. (Appellant App., Doc. 413, at 1-2).

II. Statement of Facts

Ms. Redding is a lifelong resident of Orlando, Florida, who has lived in the same neighborhood for more than 50 years. (Doc. 342, Trans.[1] Vol. 5, at 21:7-9, 24:25-25:2). She had two children, one of whom is deceased, and she has seven grandchildren, the oldest of whom is 32. (*Id.* at 21:21-22:24). She was an administrator in the Orange County public schools for 26 years. (*Id.* at 23:9-21). She worked a few other jobs after retiring from that position, and she is now fully retired. (*Id.* at 23:22-24:21).

A. Implant surgery

In 2008, Ms. Redding began having issues with her bladder. She was suffering from a bulge in her vaginal area, and from stress urinary incontinence ("SUI"), which was causing her to leak urine. (*Id.* at 35:22-37:20). In 2009, Ms. Redding visited Dr. Robert Weaver, a pelvic floor surgeon. Dr. Weaver informed

[1] "Trans." Always refers to the trial transcript. All citations are to Ms. Redding's Appendix. Citations are to the blue, electronically generated page numbers.

her that he bladder had fallen down—a condition known as pelvic organ prolapse ("POP"). (*Id.* at 57:5-9; Doc. 353, Trans. Vol. 8, at 165:12-17). Ms. Redding testified that she was having severe pain at this time. (Doc. 342, Trans. Vol. 5, at 57:18-22).

Dr. Weaver proposed mesh implant surgery to place the bladder and vagina back into their proper positions, and to "reapproximate" the bladder. (*Id.* at 39:13-15; Doc. 353, Trans. Vol. 8, at 99:5-9). Specifically, Dr. Weaver planned to implant two synthetic mesh products manufactured by Defendant Coloplast—the Supris sling to treat Ms. Redding's SUI, and the Novasilk device to treat Ms. Redding's POP. (Doc. 353, Trans. Vol. 8, at 106:8-15). Ms. Redding consented to the surgery, hoping that it would give her a more comfortable life. (Doc. 342, Trans. Vol. 5, at 40:8-11).

Dr. Weaver warned Ms. Redding that the surgery carried a risk of erosions, infections, and bleeding. (*Id.* at 39:13-40:4, 61:13-19; Doc. 353, Trans. Vol. 8, at 103:17-23). Ms. Redding signed a form warning her that with the surgery "there are significant risks, such as severe loss of blood, damage to surrounding organs, tissues, vessels, infection; any of which may necessitate a return to surgery, cardiac arrest which may result from the performance of any surgery, and in some cases may, lead to partial or permanent disability or death." (Doc. 342, Trans. Vol. 5, at

66:15-20; P186[2]). Further. Ms. Redding's pre-operative history notes: "Risk of graft erosion: Consent." (Doc. 353, Trans. Vol. 8, at 119:1-14, P157).

Dr. Weaver performed the implant surgery on December 15, 2009. (*Id.* at 991:16-18). There were no complications during this surgery, and Ms. Redding seemed to be doing fine when it was completed. (*Id.* at 122:23-123:3). When Ms. Redding returned to his office three days later, Dr. Weaver wrote "no problems" in his office note. She was not reporting any pain or odor. (*Id.* at 124:11-18, P167).

B. The "tiny erosion" spotted by Dr. Weaver

On December 28, 2009, Ms. Redding presented to Dr. Weaver for a follow-up visit. (P170). Again, she was doing well, with no leakage of urine and no complaints of pain. (Doc. 353, Trans. Vol. 8, at 125:18-21). Dr. Weaver noted a "tiny erosion," which Dr. Weaver described as being 1 by 10 millimeters. (*Id.* at 126:11-17; P170). Still, "it looked like the surgery overall had been a success other than this tiny area where the wound had opened up." (*Id*. at 126:19-21). Dr. Weaver did not document eliciting any pain during his examination of Ms. Redding, and he would have documented pain if it had occurred. (*Id.* at 127:2-7).

The phrase "tiny erosion," or a slight variation, appears in the notes of every follow-up visit that Ms. Redding had with Dr. Weaver. (P170, P171, P172, P173,

[2] "P[Number]" always refers to "Plaintiff's Exhibit [Number]." All of these cited exhibits are in Ms. Redding's Appendix.

P175). This "tiny erosion" was asymptomatic on December 28, 2009—meaning that it was not causing Ms. Redding any problems—and that fact never changed. (Doc. 353, Trans. Vol. 8, at 127:8-12; 135:7-14; 136:14-23; 139:8-12; 140:22-141:7). Dr. Weaver did not address the erosion because it was "very tiny," and he thought it would "probably heal over if we give it a chance." (*Id.* at 128:1-6; 130:4-9). He consulted with a colleague who suggested that no action beyond observation was needed. (*Id.* at 171:3-9). If the "tiny erosion" had grown, Dr. Weaver would have removed it. (*Id.* at 130:16-22). Dr. Weaver never told Ms. Redding that this "tiny erosion" was a problem for her. (*Id.* at 127:19-25).

The "tiny erosion" that Dr. Weaver observed is synonymous with a small graft exposure. (*Id.* at 105:21-106:1). Dr. Weaver testified: "I've seen several of these things before, and they're little, tiny fragments of mesh that come through the [surgical] incision." (*Id.* at 167:21-168:1). He later added: "We need to put this erosion in perspective. People … come in with these big erosions that are several centimeters in size. This is something that's like a millimeter wide that probably would heal on its own." (*Id.* at 170:3-7). Dr. Weaver never recommended removal of this "tiny erosion." If he had, it would have been a simple procedure conducted in his office with scissors. (*Id.* at 170:24-171:2). But he never felt the need to do that because it "was never bothering anything." (*Id.* at 174:14-17).

Ms. Redding testified that her memory of certain events from more than a decade prior was imperfect, and that the medical records are a better indication of what transpired than her testimony. (Doc. 342, Trans. Vol. 5, at 85:12-17). She also testified to having experienced substantial pain "like a toothache" at the time of her December 28, 2009 follow-up visit. (*Id.* at 43:1-13). Dr. Weaver did not document any pain during that visit. (P170). Dr. Weaver testified that if she had reported any pain to him, he would have documented it in the medical records. (Doc. 353, Trans. Vol. 8, at 127:2-7). When asked if she thought the products were unsafe, Ms. Redding testified: "I thought something was wrong with it, that something was just not—I don't know. Something was wrong and I—I don't know." (Doc. 342, Trans. Vol. 5, at 43:16-20). While she believed something was wrong, Ms. Redding did not know what it was. (*Id.* at 44:6-8).

By the time of her last visit to Dr. Weaver, on May 10, 2010, Ms. Redding reported: "I am doing well." (Doc. 353, Trans. Vol. 8, at 139:18-22; P175). She had no complaints of any kind of pain or discomfort. (*Id.* at 140:1-9). Ms. Redding agreed that her condition had improved by the time of her May 2010 visit with Dr. Weaver. (Doc. 342, Trans. Vol. 5, at 45:2-5). She did not return to him after that date, and she would not have stopped seeing him if she were still having problems. (*Id.* at 85:9-11).

C. Other minor issues during follow-up with Dr. Weaver

At Ms. Redding's visit on December 28, 2009, Dr. Weaver noted vaginal drainage and odor. (P170; Doc. 353, Trans. Vol. 8, at 125:18-21). The records do not note an infection, (P170), but in responding to cross-examination, Ms. Redding said Dr. Weaver told her she was infected. (Doc. 342, Trans. Vol. 5, at 69:6-8). Again, Ms. Redding had no complaints of pain at that time. (Doc. 353, Trans. Vol. 8, at 126:5-7). Dr. Weaver prescribed estrogen cream and antibiotic cream. (*Id.* at 128:1-16). When a question on cross-examination tried to connect the "tiny erosion" and Ms. Redding's alleged infection, Dr. Weaver resisted that premise. He stated he thought she "may have a vaginal infection," so he prescribed an antibiotic gel, but he "really wasn't focused on the graft as the cause." (*Id.* at 167:5-11). Infections are a risk of any surgery, with or without mesh. (*Id.* at 129:18-23).

At Ms. Redding's next visit on January 13, 2010, Dr. Weaver noted that Ms. Redding no longer had the discharge and drainage that was present at the prior visit. (*Id.* at 134:14-18). Her condition was improving. (*Id.* at 134:19-135:4). Dr. Weaver asked her to return in one month, and he would have given a shorter time frame if she was having any problems. (*Id.* at 135:25-136:6). On February 10, 2010, Ms. Redding reported that she was voiding well but had a subjective feeling that she was not fully emptying her bladder. (*Id.* at 136:14-17). That issue was

unrelated to the "tiny erosion." (*Id.* at 136:18-20). Ms. Redding had no complaints of pain or odor. (*Id.* at 136:21-25).

The next visit occurred on March 18, 2010. Ms. Redding was having urgency and frequency, and some discomfort when standing. (*Id.* at 138:10-11; P173). A urine sample was negative. (*Id.* at 139:2). This discomfort while standing is a different symptom from what she experienced years later—severe pelvic pain, vaginal pain, and dyspareunia—i.e., pain with sex. (*Id.* at 138:15-21). The "tiny erosion" remained asymptomatic. (*Id.* at 139:8-12).

On May 10, 2010, Ms. Redding saw Dr. Weaver for the last time. He reported that she said: "I am doing well." (P175). She had no complaints of any kind of pain, or of discomfort with standing. (Doc. 353, Trans. Vol. 8, at 140:1-6). Her only complaint was about a slow stream, which Dr. Weaver diagnosed as a bladder obstruction. That issue was unrelated to the "tiny erosion." (*Id.* at 140:17-21; 142:9-20). Dr. Weaver noted that there were no abnormalities, and he did not see any other issues with Ms. Redding. (*Id.* at 141:12-14). Again, Ms. Redding testified that her symptoms improved over time, and that she would not have stopped seeing Dr. Weaver if she were still having problems at that time. (Doc. 342, Trans. Vol. 5, at 45:2-5; 85:9-11).

Ms. Redding was not told that the mesh was defective or unsafe. (*Id.* at 46:13-17). Dr. Weaver testified that he never told Ms. Redding about any defect or

lack of safety regarding the Coloplast mesh products that he used. (Doc. 353, Trans. Vol. 8, at 141:15-19). Nor did he tell her, at any time, that there was anything wrong with the mesh. (*Id.* at 141:20-23).

To summarize the above, based on the medical records and the treating physician's testimony, the only complications that Ms. Redding suffered during her time seeing Dr. Weaver in 2009-10 were:

- A "tiny erosion" that Dr. Weaver described as "asymptomatic" and did not feel was necessary to treat.[3] Dr. Weaver had warned Ms. Redding that erosions were a risk of this surgery.
- Post-surgical discharge and drainage, possibly due to infection, which resolved. Dr. Weaver had warned Ms. Redding that infections were a risk of this surgery.
- Some discomfort with standing that resolved.
- Some minor voiding difficulties, unrelated to the "tiny erosion," that mostly resolved, other than a bladder obstruction—and she had bladder issues before surgery.

[3] Dr. Lennox Hoyte, a Florida-based pelvic floor surgeon with a master's degree from MIT and a medical degree from Stanford, was an expert witness for the Plaintiff. (Doc. 351, Trial Tr. Vol 7, at 22:1-19). He agreed with Dr. Weaver's decision not to treat the "tiny erosion" because they often heal on their own with time. (*Id.* at 54:18-55:1). He further opined that the small erosion did, in fact, resolve with time. (*Id.* at 55:20-23).

Less than five months after surgery, Ms. Readding reported: "I am doing well" and stopped seeing Dr. Weaver.

D. Ms. Redding's two surgeries in 2014

For almost four years, there are no records of Ms. Redding having any physician visits related to her mesh products. (Doc. 351, Trans. Vol 7, at 56:4-19). But Ms. Redding visited Dr. Jan Parrillo on May 1, 2014, (*id.*), and then saw Dr. Steven McCarus on June 12, 2014. (Doc. 344, Trans. Vol. 6, at 26:12-17). Dr. McCarus examined Ms. Redding, finding that the urethra and the bladder had prolapsed. He also observed mesh eroding through her tissue. (P148 at 4; Doc. 344, Trans. Vol. 6, at 27:16-28:1). Dr. McCarus performed surgery five days later. His pre-operative diagnosis was postmenopausal bleeding, pelvic pain, and vaginal mesh erosion. (P149 at 1; Doc. 344, Trans. Vol. 6, at 28:20-24). Dr. McCarus defined "erosion" as "an abnormal change in an area that would cause discomfort or bleeding. So when you place a foreign body in the tissue, it can heal up, and if it doesn't heal up, then it can erode into that tissue around the foreign body." (Doc. 344, Trans. Vol. 6, at 29:25-30:6). Dr. Hoyte agreed with Dr. McCarus's diagnosis of a mesh erosion. (Doc. 351, Trans. Vol. 7, 58:9-59:9).

Dr. McCarus removed the eroded mesh during surgery, and Ms. Redding's bleeding stopped. (Doc. 344, Trans. Vol. 6, at 31:21-32:2). Dr. McCarus testified, to a reasonable degree of medical probability, that the mesh erosion caused Ms.

Redding's pelvic pain. (*Id.* at 33:18-22). He decided to remove part of her mesh because it was necessary to resolve Ms. Redding's bleeding and help with her pain. (*Id.* at 34:17-35:2). The pathology report indicates that the mesh was "entangled," which Dr. McCarus said means that it "looks like a picket fence." (P162 at 2; Doc. 344, Trans. Vol. 6, at 37:2-4).

Dr. McCarus performed a second surgery on July 22, 2014. The surgery was a hysterectomy designed to help with Ms. Redding's prolapse issues, but he also observed additional eroded mesh, which he removed. (Doc. 344, Trans. Vol. 6, at 40:8-16; P151 at 2). Dr. McCarus's two mesh excisions were taken from different parts of the vaginal region—one at the mid-urethra, and one at the bladder neck. (*Id.* at 43:19-23). Both erosions were larger than the "tiny erosion" observed by Dr. Weaver. The first excision removed tissue measuring 1.5 by 1.5 by 0.3 cm, with five "entangled" mesh pieces measuring a total of 0.8 by 0.8 by 0.2 cm. (P162 at 2). The mesh removed in the second surgery measured 1 cm by 0.7 cm by 0.4 cm. (P152 at 2; Doc. 344, Trans. Vol. 6, at 46:13-18).

Per Dr. Hoyte, Ms. Redding's presentation to Dr. McCarus in 2014 marked the first time she had an erosion with postmenopausal bleeding, and was the first time she complained of pelvic pain. (Doc. 351, Trans. Vol. 7, at 59:10-20; 60:23-61:11). Her complaints of postmenopausal bleeding and pelvic pain were in different areas from the "tiny erosion" spotted by Dr. Weaver. (*Id.* at 61:20-62:4).

Both areas where Dr. McCarus excised eroded mesh were far from the location of the prior "tiny erosion." (*Id.* at 62:17-24).

E. Ms. Redding's continuing mesh-related problems

Ms. Redding visited Dr. McCarus again in February 2017, complaining of urinary incontinence and pain. (P180 at 2; Doc. 344, Trans. Vol. 6, at 47:14-17). She told Dr. McCarus that she was leaking urine every day. (*Id.* at 47:18-23). Ms. Redding visited Dr. McCarus again in September 2018. She was suffering from pelvic pain and vulvovaginal atrophy, meaning her vaginal tissue was thin, like a cracker, instead of soft like it was supposed to be. (P184 at 3; Doc. 344, Trans. Vol. 6, at 48:25-49:9).

Later in 2018, Ms. Redding saw a new physician. Dr. Rakesh Patel. She presented to Dr. Patel with symptoms of dyspareunia, urine incontinence, vaginal pain, and intermittent vaginal discharge. (P181 at 3; Doc. 355, Trans. Vol. 9, at 47:22-48:7). Upon examination, Dr. Patel could feel a hard foreign body under Ms. Redding's vaginal lining. If he pushed on it, Ms. Redding experienced pain. This typically results from the mesh pulling on a muscle or structure where it is attached. (*Id.* at 49:10-20). This testimony fits with Dr. McCarus's concern that Ms. Redding's mesh was "contracting or migrating or moving." (Doc. 344, Trans. Vol. 6, at 73:3-7). Dr. Patel's findings refer to a "mesh band," which means that he felt a scar, and it is "almost a rope-like firm structure. So it's not normal vaginal

tissue or not a normal scar you would have from a healing incision." (Doc. 355, Trans. Vol 9, at 49:23-50:3). Dr. Patel opined that the mesh caused Ms. Redding's chronic vaginal pain and dyspareunia. (*Id.* at 53:23-54:7).

Ms. Redding returned to Dr. McCarus in 2022. She was complaining of urinary frequency and pelvic pain. (Doc. 344, Trans. Vol. 6, at 49:16-21). She was tender on examination. (*Id.* at 50:8-12). Dr. McCarus testified that Ms. Redding has consistently battled pelvic pain during the eight-year period in which he has treated her, and in his opinion the Coloplast mesh caused that pain. (*Id.* at 52:3-11).

Dr. Hoyte did a full physical examination of Ms. Redding after being retained for the case. He found tight scarring on the anterior vaginal wall, as well as foreign bodies that he palpated on the anterior vaginal wall and at the bladder neck. There was scarring, and the foreign bodies were tight, pulled together, and contracted. When he palpated them, he elicited pain. (Doc. 351, Trans. Vol. 7, at 72:17-73:5).

Based on his examination and study of the case, Dr. Hoyte opined that Ms. Redding has suffered harms related to mesh contracture and shrinkage. She has suffered vaginal bleeding due to mesh erosion. She has suffered chronic pelvic pain due to mesh contraction and scarring, and urinary incontinence due to mesh removal. (*Id.* at 36:15-25). Dr. Hoyte testified that erosions can happen years after mesh is implanted, and in his opinion this happened to Ms. Redding. (*Id.* at 83:24-

84:3). The mesh contraction/shrinkage that is causing Ms. Redding's pain also would not likely have occurred immediately after implant. Those events do not happen in the short term, Dr. Hoyte explained. (*Id.* at 39:11-19).

The majority of the mesh implanted in Ms. Redding remains in her. (*Id.* at 71:9-12). Per Dr. Hoyte, that mesh may continue causing irritation and foreign body reaction. Her pain may get worse, and it is more likely than not that she will suffer from another mesh erosion. (*Id.* at 90:3-12).

III. Standard of Review

Coloplast appeals from the denial of its motion for judgment notwithstanding the verdict. This Court applies the same standard of review that the district court applied in adjudicating the motion. *Ortega v. Schramm*, 922 F.2d 684, 694 (11th Cir. 1991). That standard is:

> *All* of the evidence presented at trial must be considered "in the light and with all reasonable inferences most favorable to the party opposed to the motion." A motion for judgment n.o.v. should be granted only where "reasonable [people] could not arrive at a contrary verdict...." Where substantial conflicting evidence is presented such that reasonable people "in the exercise of impartial judgment might reach different conclusion, [sic]" the motion should be denied.

Id. (quoting *Simon v. Shearson Lehman Bros., Inc.*, 895 F.2d 1304, 1310 (11th Cir. 1990)).

SUMMARY OF THE ARGUMENT

The standard of review requires this Court to consider all of the evidence and view it in the light most favorable to Ms. Redding. Coloplast's brief takes the opposite approach by ignoring the vast majority of the evidence and viewing the evidence cited in the light most favorable to Coloplast. In addition, Coloplast has twisted the key facts into a pretzel.

Coloplast asserts that "[m]ore than four years before she sued, Plaintiff was diagnosed with pelvic pain caused by an erosion of the mesh device—the condition that is the premise of her lawsuit." (Aplt. Br. at 17). This statement is inaccurate, and Coloplast's entire argument builds on the idea that Dr. Weaver "diagnosed" a mesh erosion that **caused** Ms. Redding to suffer pain in 2009 and 2010.

In reality, Dr. Weaver never diagnosed the "tiny erosion" that he observed as causing pelvic pain or any other symptom. In fact, he did not document Ms. Redding having any pain at all during the period in which he treated her—which is the only period relevant to the statute of limitations. Based on the medical records and physician testimony, there is no basis to conclude that the mesh injured Ms. Redding in 2009 or 2010. The only **possible** basis for such a conclusion is some cryptic testimony from Ms. Redding. But the jury was free to rely on the medical records and the physicians' testimony, rather than Ms. Redding's admittedly unclear memories.

Taking the evidence in the light most favorable to the jury's verdict, there are two clear reasons why the verdict should stand. First, a reasonable jury could find that Ms. Redding did not suffer a compensable injury before September 2010. Under Florida law, "a cause of action cannot be said to have accrued … until an action may be brought." *State Farm Mut. Auto. Ins. Co. v. Lee*, 678 So. 2d 818, 821 (Fla. 1996). Ms. Redding had no basis to bring an action against Coloplast in 2009 or 2010. There is no documentation of pain or infection in her medical records, and if there was an infection, it quickly resolved. By the time Dr. Weaver stopped treating her in May 2010, she was "doing well."

Second, under Florida law an action does not accrue until "the date that the facts giving rise to the cause of action were discovered, or should have been discovered with the exercise of due diligence." *Eghnayem v. Bos. Sci. Corp.*, 873 F.3d 1304, 1323 (11th Cir. 2017) (quoting Fla. Stat. § 95.031(2)(b)). No physician told Ms. Redding that her implanted mesh was causing any problems for her in 2009 or 2010. Instead, Dr. Weaver described her erosion as "asymptomatic." Thus, a reasonable jury could conclude that her cause of action had not accrued.

Finally, this Court should reject the invitation to send a certified question to the Florida Supreme Court. This Court has twice decided the same issues without seeking guidance from the Florida Supreme Court. The proposed certified question also misrepresents the facts—Coloplast again claims that someone diagnosed an

erosion causing pelvic pain during the relevant timeframe—and the Florida Supreme Court could not take the case because the question is not dispositive. For these and other reasons, almost every factor used to determine whether to send a certified question counsels against doing so here.

This Court, therefore, should affirm the district court's denial of the motion for judgment notwithstanding the verdict.

ARGUMENT

This Court should affirm the denial of Coloplast's motion for judgment notwithstanding the verdict ("j.n.o.v."). First, a reasonable jury could find that Ms. Redding did not suffer a compensable injury before September 28, 2010, the date that is four years before filing. *See* Fla. Stat. § 95.11(3)(e) (limitations period is four years). Second, a reasonable jury could find that Ms. Redding neither discovered, nor should have discovered, her cause of action before the four-year limitations period began. Further, there is no need to send a certified question to the Florida Supreme Court.

I. This Court should affirm the denial of Coloplast's j.n.o.v. motion because reasonable jurors could conclude that the Coloplast mesh did not harm Ms. Redding before the limitations period, or that Ms. Redding did not discover, and could not have reasonably discovered, her claims before the limitations period.

The first step for this Court in evaluating the district court's denial of Coloplast's j.n.o.v. motion is to consider **all** of the evidence. *See, e.g.*, *Martinez v. City of Opa-Locka, Fla.*, 971 F.2d 708, 711 (11th Cir. 1992). Coloplast's statute of limitations argument cites no medical records; cites no testimony from Dr. Weaver, except in describing Ms. Redding's prior arguments; and cites no testimony from Dr. Hoyte, Ms. Redding's case-specific expert. (*See* Aplt. Br. at 22-38). Coloplast's argument is based almost entirely on Ms. Redding's lay testimony.

The medical records and physician testimony demonstrate that Ms. Redding's claims did not accrue in 2009 or 2010. Ms. Redding filed this case on September 28, 2014, and the applicable statute of limitations is four years. Thus, the key question is whether Ms. Redding's claims accrued before September 28, 2010. (*See id.* at 1). By that date, Ms. Redding had no compensable injury, and had neither discovered nor had reason to discover an injury caused by the mesh. Therefore, the limitations period had not begun running.

A. The evidence, viewed the light most favorable to the verdict, shows that Ms. Redding could not have brought a claim in 2010 because she had not suffered an injury caused by mesh.

1. Coloplast must prove that Ms. Redding indisputably suffered a compensable injury before September 2010.

Based on Florida law and common sense, the limitations period cannot begin running until the plaintiff has a basis to file a claim. Fla. Stat. § 95.031(1) ("A cause of action accrues when the last element constituting the cause of action occurs."). In addressing Ms. Redding's prior argument on this point, Coloplast cites language that the limitations period begins running when "an injury, although slight, is sustained in consequence of [a] wrongful act." (Aplt. Br. at 34 (citing *Kipnis v. Bayerische Hypo-Und Vereinsbank, AG*, 202 So. 3d 859, 862 (Fla. 2016), *opinion after certified question answered*, 844 F.3d 944 (11th Cir. 2016)). But that same case made clear that a cause of action cannot accrue until "an action may be brought." *Id.* at 861-62 (quoting *Lee*, 678 So. 2d at 821). The argument is not that

the mesh caused a minor injury in 2009 and 2010 that worsened later. The evidence shows that the mesh did not cause **any** injury giving rise to a claim in 2009 and 2010.

Determining when the statute of limitations period begins is a question of fact, and therefore it cannot be determined as a matter of law "if there is a genuine question as to when it began to run." *Boneta v. Am. Med. Sys., Inc.*, 524 F. Supp. 3d 1304, 1310 (S.D. Fla. 2021) (citing *Morton's Mkt., Inc. v. Gustafson's Dairy, Inc.*, 198 F.3d 823, 828 (11th Cir. 1999)). The party raising the statutory defense "must conclusively show that there exists no disputed issue of fact with respect to the date of commencement of the limitations period." *Id.* (quotations omitted). As laid out below, the evidence does not support such a showing here.

2. The medical records and physician testimony strongly support concluding that Ms. Redding suffered no compensable injury before September 2010.

Viewing the evidence in the light most favorable to the jury's verdict, Ms. Redding had no basis to bring an action against Coloplast before September 2010. The medical records and physician testimony would not support such a claim, and the jury was free to give greater weight to that evidence. *See Ray v. Sun Life & Health Ins. Co.*, 752 F. Supp. 2d 1229, 1246 (N.D. Ala. 2010), *aff'd*, 443 F. App'x 529 (11th Cir. 2011) (holding that opinions supported by the medical records "constitute more reliable evidence"); *McRevy v. Ryan*, No. CIV.A. 08-508-CG-B,

2010 WL 749327, at *3 (S.D. Ala. Feb. 26, 2010), *aff'd*, 405 F. App'x 400 (11th Cir. 2010) (holding that plaintiff had made a submissible case but "defense counsel elicited testimony and pointed out discrepancies in the medical records that would support a completely contrary verdict").

The medical records and testimony refute Coloplast's arguments. Coloplast's primary contention is that someone "diagnosed" Ms. Redding "with pelvic pain caused by an erosion of the mesh device." (Aplt. Br. at 17; *see also. id.* at 36). Dr. Weaver, who implanted the mesh and treated Ms. Redding from her December 15, 2009 implant until her final visit on May 10, 2010, never diagnosed Ms. Redding with pelvic pain—period. He also never diagnosed Ms. Redding's "tiny erosion" as causing any problems.

As laid out above, Dr. Weaver observed this "tiny erosion" during a follow-up visit thirteen days after implanting the two Coloplast mesh products. (P170). The "tiny erosion" was asymptomatic on that date, and it remained asymptomatic during all of Ms. Redding's follow-up visits with Dr. Weaver. (Doc. 353, Trans. Vol. 8, at 127:8-12, 135:7-14, 136:14-23, 139:8-12, 140:22-141:7). Ms. Redding did not complain of pain during the December 28, 2009 visit. (*Id.* at 126:5-10). If Ms. Redding had complained of pain, Dr. Weaver would have documented that fact. (*Id.* at 127:2-7).

There is no documentation of "pelvic pain" in any record of Ms. Redding's visits to Dr. Weaver. (P170, P171, P172, P173, P175). Dr. Hoyte testified that when Ms. Redding suffered postmenopausal bleeding and pelvic pain in 2014, these were first-time symptoms. (Doc. 351, Trans. Vol. 7, at 59:10-20; 60:23-61:11). Clearly, a reasonable jury could determine that Ms. Redding's "tiny erosion" did not cause pelvic pain, when there is no medical record documenting pelvic pain at all.

Notably, Dr. Weaver never treated the "tiny erosion." Presumably, he would have done so if it were causing pain, as Coloplast suggests. Dr. Weaver could have removed the eroded mesh in his office with scissors, but he never did so because it "was never bothering anything." (Doc. 353, Trans. Vol. 8, at 170:24-171:2, 1059:14-17). Ms. Redding did report "discomfort with standing" at one visit. (P173; Doc. 353, Trans. Vol. 8, at 138:6-11). But Dr. Weaver does not believe that issue was related to her "tiny erosion," (Doc. 353, Trans. Vol. 8, at 139:8-12), and it quickly resolved by her next visit. (*Id.* at 140:1-6).

Coloplast is also incorrect in suggesting that Dr. Weaver **diagnosed** Ms. Redding has having an infection caused by her mesh implants. (Aplt. Br. at 24). The records of Ms. Redding's December 28, 2009 visit note a vaginal discharge, drainage, and odor. (P170; Doc. 353, Trans. Vol. 8, at 125:18-21). The records do not note an infection. (P170). Dr. Weaver prescribed an antibiotic cream in case

she had an infection. If it was an infection, he "really wasn't focused on the graft as the cause." (Doc. 353, Trans. Vol. 8, at 167:5-11). Any surgery can lead to infections, with or without mesh. (*Id.* at 129:18-23). Ms. Redding's condition was improved sixteen days later, at her follow-up appointment on January 13, 2010. (*Id.* at 134:14-135:4). Ms. Redding testified that she had an infection at her May 2010 visit with Dr. Weaver, (Doc. 342, Trans. Vol. 5, at 73:17-21), but he disagrees. He testified that she had no drainage or odor, he had no concern about infection at that time, and he did not tell Ms. Redding that she had an infection. (Doc. 353, Trans. Vol. 8, at 140:10-16).

There is no evidence causally linking the "tiny erosion" to any harm that Ms. Redding may have suffered in 2009 or 2010. As such, it was eminently reasonable for the jury to find that Ms. Redding timely filed her claim.

3. The medical records and testimony demonstrate that Ms. Redding suffered new injuries in 2014.

Another Coloplast argument contradicted by the evidence is its claim that the injuries Ms. Redding suffered in 2014 and beyond are the same injuries she sustained in 2009 and 2010. (Aplt. Br. at 25). Again, the medical records and the testimony of the treating physicians and Dr. Hoyte tell a different story.

Dr. Hoyte opines that the "tiny erosion" observed by Dr. Weaver likely resolved on its own, over time. (Doc. 351, Trial. Tr. Vol. 7, at 54:18-55:23). In 2014, Ms. Redding suffered from new symptoms—specifically, pelvic pain and

postmenopausal bleeding. Dr. McCarus twice performed surgery to excise eroded mesh from Ms. Redding. (*Id.* at 59:10-20, 60:23-61:11; P149; P151). Her complaints of postmenopausal bleeding and pelvic pain were in different areas from the "tiny erosion" spotted by Dr. Weaver. (*Id.* at 61:20-62:4).

Both areas where Dr. McCarus excised eroded mesh were far from the location of the prior "tiny erosion." (*Id.* at 62:17-24). And, each of the two erosions excised in 2014 was larger than the old erosion that Dr. Weaver described as being 1 mm by 10 mm. (Doc. 353, Trans. Vol. 8, at 126:11-17; P162 at 2; P152 at 2; Doc. 344, Trans. Vol. 6, at 46:13-18).

Dr. Hoyte opined that mesh erosions often occur years after implant, and he believes that occurred in Ms. Redding's case. (Doc. 351, Trial. Tr. Vol. 7, at 83:24-84:3). Dr. Hoyte also blames mesh contraction/shrinkage for Ms. Redding's pain, and shrinkage would likely not have occurred immediately after implant. (*Id.* at 39:11-19).

Of course, the physicians' reaction to the two situations was also vastly different. In 2010, when the "tiny erosion" was asymptomatic, Dr. Weaver determined that it was not necessary to intervene. (Doc. 353, Trans. Vol. 8, at 171:3-9). Dr. Hoyte agreed with that decision. (Doc. 351, Trial. Tr. Vol. 7, at 54:18-55:1). Conversely, Dr. McCarus performed surgery five days after first seeing Ms. Redding, and he performed a second surgery the next month. (Doc.

344, Trans. Vol. 6, at 28:20-24, 38:14-39:4; P151). Clearly, what she was experiencing in 2014 was much worse than what she had experienced in 2009 and 2010.

From this evidence, a reasonable jury could find that Ms. Redding suffered new injuries in 2014, rather than continuing the same "injuries" she supposedly suffered during the post-surgical period. Therefore, a reasonable jury could find that the limitations period did not run until the mesh removal surgeries in 2014.

4. Ms. Redding's testimony that contradicts the medical records does not establish as a matter of law that she was injured by the mesh in 2009 or 2010.

As noted, Coloplast's argument relies almost entirely on Ms. Redding's testimony, which contradicts the medical records. Thus, the key question is whether the jury was required to both credit her testimony and interpret it in Coloplast's favor. The answer, of course, is no. *See Amegy Bank Nat'l Ass'n v. Deutsche Bank Alex.Brown*, 619 F. App'x 923, 931 (11th Cir. 2015) (stating that this Court's ability "to set aside a jury verdict is more constrained," and that the Court "give[s] particular deference to credibility determinations of a fact-finder who had the opportunity to see live testimony").

Notably, Ms. Redding herself agreed that her memory of events from more than a decade prior was imperfect, and that the medical records would be a better way to determine what occurred. (Doc. 342, Trans. Vol. 5, at 85:12-17). As to Ms.

Redding's alleged injuries—as opposed to her knowledge thereof—Coloplast primarily relies on three statements, all of which contradict the medical records. One is that she had sharp pain, "like a toothache," at the time of her follow-up visit thirteen days after surgery. (Aplt. Br. at 33 (citing Doc. 342, Trans. Vol. 5, at 43:1-13)). Again, Dr. Weaver did not document any complaints of pain, and he would have noted any pain complaints. (P170; Doc. 353, Trans. Vol. 8, at 127:2-7). The word "pain" does not appear in the post-surgery follow-up records. (*See* P170, P171, P172, P173, P175). Thus, the jury could reasonably have determined that she misremembered. Or, the jury could have determined that she had some pain related to the surgery, only thirteen days after the procedure. But nothing in the records or the physicians' testimony supports the argument that the "tiny erosion" caused Ms. Redding to suffer severe pain at that time.

Ms. Redding also testified that she felt that her bulge had returned, that she had discomfort while standing, and had difficulty emptying her bowels. (Aplt. Br. at 33 (citing Doc. 342, Trans. Vol. 5, at 71:19-73:2)). Nothing about the "bulge" returning appears in the medical records for that March 18, 2010 visit. (P173). Regardless, the "bulge" returning would not be an injury caused by the mesh, as it was an issue pre-surgery. (Doc. 342, Trans. Vol. 5, at 55:15-17). Dr. Weaver testified that the discomfort from standing was unrelated to the tiny erosion, which remained asymptomatic. (Doc. 353, Trans. Vol. 8, at 139:8-12). It was also a

different symptom from the various symptoms she experienced in 2014 and beyond. (*Id.* at 138:12-21). Nothing about difficulty with bowel movements appears in that March 18, 2010 record, (P173), and nothing at trial established that Ms. Redding's mesh caused difficulty with bowel movements.

Coloplast also cites testimony where Ms. Redding simply agreed on cross-examination that her 2014 complaints were the same as her complaints in May 2010, when she last saw Dr. Weaver. (Aplt. Br. at 33 (citing Doc. 342, Trans. Vol. 5, at 76:20-24)). The records and even Ms. Redding's other testimony contradict this response. She was clearly having major issues in 2014, as she had two surgeries one month apart. (P149; P151). In May 2010, she told Dr. Weaver: "I am doing fine," and then she stopped seeing him. (Doc. 353, Trans. Vol. 8, at 139:18-22; P175). She testified that she would not have stopped seeing Dr. Weaver if she were still having problems. (Doc. 342, Trans. Vol. 5, at 85:9-11). She reported no pain or discomfort at that May 2010 visit. (P175; Doc. 353, Trans. Vol. 8, at 140:1-16). She was clearly having pain in 2014, as she was bleeding from the vagina. (P149; Doc. 344, Trans. Vol. 6, at 28:20-24). Ms. Redding testified that she suffered an infection in May 2010, but the records do not mention an infection. (P175). Plus, Dr. Hoyte testified that physicians, not patients, determine whether a patient has an infection. (Doc. 353, Trans. Vol. 8, at 25:12-20).

For these reasons, Ms. Redding's testimony does not establish, as a matter of law, that Coloplast's mesh injured her by September 2010. *See United States v. Siegelman*, 640 F.3d 1159, 1165 (11th Cir. 2011) (holding that to the extent a jury's verdict turns on the inferences to be drawn from a witness's testimony, "we owe deference to those decisions").

5. A recent statute of repose case provides a helpful analysis.

On the issue of whether the mesh injured Ms. Redding in 2009 or 2010, a recent Sixth Circuit case addressing a statute of repose is instructive. *See Parton v. Johnson & Johnson*, 821 F. App'x 601 (6th Cir. 2020). Because the Tennessee statute of repose ran from the time of "injury," the question was whether pelvic pain suffered shortly after surgery triggered the statutory period. *Id.* at 602-03.

The patient, Parton, testified that her pelvic pain "got worse" after mesh implant surgery. *Id.* at 603. The Sixth Circuit viewed the evidence in the light most favorable to the plaintiff and held that the testimony did not conclusively establish that the mesh caused Parton's pain. Further, Parton was only competent to testify about her symptoms, and not about what was causing them. *Id.* at 603-04. Thus, the court reversed summary judgment and remanded the case. *Id.* at 604.

The argument against judgment as a matter of law is much stronger here, as *Parton* simply assessed whether a patient's testimony, alone, established an injury.

There is no indication in the opinion that medical records and physician testimony strongly suggested the absence of injury, as is the case here.

Whether the jury could have credited Ms. Redding's testimony over contrary information from the medical records and medical providers is an interesting question, but one this Court does not have to answer. The issue is whether a reasonable jury could determine that Ms. Redding suffered no injury caused by Coloplast's mesh products in 2009 and 2010, when the medical records and medical testimony support that conclusion. *See* Fla. Stat. § 95.031(1) ("A cause of action accrues when the last element constituting the cause of action occurs."). The clear answer is "yes," when viewing the evidence in the light most favorable to the verdict, as the law requires. *See United States v. Almanzar*, 634 F.3d 1214, 1223 (11th Cir. 2011) (reversing decision where "the district court disregarded its duty to view the evidence in a light most favorable to the jury's verdict").

The district court, therefore, properly denied the motion for judgment notwithstanding the verdict.

B. Reasonable jurors could conclude that the limitations period did not begin running in 2010 because Ms. Redding did not know, and did not have reason to know, that Coloplast's mesh products caused injury to her.

When the district court thrice denied Coloplast's motions on the statute of limitations issue, it relied primarily on the discovery rule.[4] Fla. Stat. § 95.031(2)(b). That rule also provides a basis to reject Coloplast's appeal. Coloplast has not established, as a matter of law, that Ms. Redding knew or should have known by September 2010 that Coloplast's mesh had injured her.

1. The district court properly set out the legal standard in applying Florida's discovery rule, as declared by this Court.

Contrary to Coloplast's argument, the district court properly applied Florida law, as set out by this Court. The issue under the discovery rule is whether Ms. Redding "discovered, or should have … discovered with the exercise of due diligence" the "facts giving rise to the cause of action" before September 2010. Fla. Stat. § 95.031(2)(b).

In denying Coloplast's first Rule 50 motion, the district court applied this Court's precedent in *Eghnayem*, which requires "an injury distinct in some way from conditions naturally to be expected from the plaintiff's condition," plus a causal connection to the product at issue. *Eghnayem*, 873 F.3d at 1323 (quoting

[4] Of course, this Court may affirm the judgment for any reason supported by the law and record. *United States v. Chitwood*, 676 F.3d 971, 975 (11th Cir. 2012).

Babush v. Am. Home Prods. Corp., 589 So.2d 1379, 1381 (Fla. Dist. Ct. App. 1991)). The district court held that there was "sufficient evidence for a reasonable jury to conclude that Plaintiff was not aware of 'an injury distinct in some way from conditional naturally to be expected from' her implantation and that such injury was causally connected to Defendant's products until after September 28, 2010." (Dkt. 405 at 7).

Coloplast erroneously asserts that the district court misapplied *Eghnayem*. It claims that the district court "stretched *Eghnayem* well past its breaking point," (Aplt. Br. at 31). But it is Coloplast's argument that is stretching the district court's analysis past its breaking point. The trial court's Rule 50 decisions did not rely on the similarities between *Eghnayem* and this case. The district court simply took the standard from *Eghnayem*—which is derived from Florida law—and applied it to these facts. (Dkt. 405 at 6-7).[5] Coloplast also cites to the court's summary judgment order, but that order is not appealable post-trial. *Lind v. United Parcel Serv., Inc.*, 254 F.3d 1281, 1286 (11th Cir. 2001).

Coloplast has identified no legal error by the court in applying Florida law, as laid out in *Eghnayem*. Coloplast's claim relate entirely to the **application** of that law to the facts, which is addressed below.

[5] The trial court did not include additional legal analysis in ruling on the renewed motion for judgment as a matter of law, as Coloplast advanced no new arguments. (Appellant App., Dkt. 413, at 1-2).

2. The district court properly held that the evidence supported a jury finding that Ms. Redding's cause of action did not accrue by September 2010.

As the district court held, the evidence supported the jury's conclusion if it was based on the discovery rule. (Appellant App., Dkt. 405, at 7). Ms. Redding did not know, or have reason to know, that there was a causal connection between any injury she may have suffered by September 2010 and Coloplast's products. To prevail, Coloplast must convince this Court that the evidence in its favor "is so overwhelmingly in favor of [Coloplast] that a reasonable jury could not arrive at a contrary verdict." *Middlebrooks v. Hillcrest Foods, Inc.*, 256 F.3d 1241, 1246 (11th Cir. 2001).

This Court has twice distilled the issue, under Florida law, as turning on "whether the injuries suffered after contact with a product were 'sufficiently dramatic to provide notice' that something might be wrong with the product." *Perryman v. Mentor Worldwide LLC (In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.)*, 748 F. App'x 212, 217 (11th Cir. 2018) (quoting *Eghnayem*, 873 F.3d at 1324). This standard applies because Florida law requires knowledge of a "causal connection" between the product and the injury. *Id.* at 216. Under Florida law, the limitations period does not run until a plaintiff has "actual or constructive knowledge of a *causal* connection between the product and her injury. And this causal connection requires knowledge of a reasonable possibility

of a **defect**." *Boneta*, 524 F. Supp. 3d at 1314 (citing *Eghnayem*, 873 F.3d at 1324) (bold emphasis added).

This Court in *Perryman* reversed summary judgment for the defendant, holding that the plaintiff's post-surgery symptoms "could arise from a nondefective mesh that had been implanted through surgery that was properly performed." *Id.* at 217. In *Eghnayem*, the plaintiff had a new symptom—urinary incontinence—during the pre-limitations period, but it "was not so obviously unusual as to indisputably put Eghnayem on notice about her claim." *Eghnayem*, 873 F.3d at 1324.

The trial court properly reached the same conclusion here. The first reason is laid out in the prior section. Because Ms. Redding did not have an injury caused by mesh by September 2010—or, at least, a reasonable jury could so conclude—she could not have known of such an injury. *See supra*, § I.A.

The evidence also supports concluding that Ms. Redding's symptoms were insufficient to put her on notice of a claim against Coloplast. Critically, her treating physician did not believe that there was a problem with the mesh, did not tell Ms. Redding that there was a problem with the mesh, and did not treat her "tiny erosion." The expert on the matter, Dr. Weaver, gave Ms. Redding no reason to believe that any defect in Coloplast's mesh was causing her injuries.

In a recent mesh case, the Seventh Circuit reversed a summary judgment for the manufacturer, based on the statute of limitations, on facts far more dramatic than the evidence here. *See Stark v. Johnson & Johnson*, 10 F.4th 823 (7th Cir. 2021).[6] The plaintiff had several mesh revision surgeries—i.e., the event that caused Ms. Redding to file suit three months later—before the limitations period. *Id.* at 826-27. But she had a condition that contributes to poor wound healing, and her physicians never told her that the mesh was the problem. *Id.* at 829-30. The Court of Appeals placed great weight on that fact, stating:

> Medical treatment of human disease can be complex and full of uncertainty. Success is not guaranteed, and a surgery's "failure" or shortcomings should not necessarily be sufficient to tell a patient that she should start investigating possible claims against her physicians or the manufacturers of the products they used. Although we have made this point repeatedly in medical malpractice cases, it applies with equal force to product liability claims, where patients often confront similar circumstances: faced with some illness or injury, a patient seeks counsel from a trusted physician, follows the physician's suggested course of treatment, and then experiences an unfortunate outcome.
>
> That unfortunate outcome, by itself, is not sufficient to start the statute of limitations clock.

Id. at 836.

[6] The Illinois discovery rule is similar to Florida's, holding that "the statute of limitations clock does not start running until the injured party knows or reasonably should have known both that she was injured and that her injury was wrongfully caused by another person." *Id.* at 828.

The same reasoning applies here. Ms. Redding was a school administrator who had no medical training. (Doc. 342, Trans. Vol. 5, at 23:9-21; 42:3-4). Dr. Weaver never told Ms. Redding that the Coloplast mesh was defective or unsafe. (*Id.* at 46:13-17). He never told her that there was anything wrong with the mesh. (Doc. 353, Trans. Vol. 8, at 141:20-23). Ms. Redding knew that she had a "tiny erosion," but Dr. Weaver never told her that it was problem. (*Id.* at 127:19-25). She could reasonably rely on the absence of any indication from Dr. Weaver that her mesh was defective or problematic. *See Stark*, 10 F.4th at 836. Ms. Redding did not have reason to know that she was injured by a defect in the mesh. *Boneta*, 524 F. Supp. 3d at 1314.

Again, the "tiny erosion" that Dr. Weaver observed was asymptomatic. (Dkt. 353, Trans. Vol. 8, at 127:8-12; 135:7-14; 136:14-23; 139:8-12; 140:22-141:7). He determined that it was unnecessary to treat the "tiny erosion" because it was not growing and "was never bothering anything." (*Id.* at 174:6-22). The discharge, drainage, and odor observed thirteen days after surgery may have been an infection, but Dr. Weaver was unsure. (*Id.* at 167:5-11). Infection is a risk of any surgery, and even if Ms. Redding had one, he did not connect it to the "tiny erosion." (*Id.* at 129:18-23; 167:5-11). She later complained of "discomfort with standing," which was also unrelated to the "tiny erosion." (P173; Doc. 353, Trans. Vol. 8, at 138:10-11, 139:8-12). That symptom resolved by her next visit, and it

was unrelated to the symptoms Ms. Redding suffered years later. (*Id.* at 140:1-6; 138:15-21).

Applying Florida law, as interpreted twice by this Court in mesh cases, Ms. Redding did not have injuries that "were 'sufficiently dramatic to provide notice' that something might be wrong with the product." *Perryman*, 748 F. App'x at 216 (quoting *Eghnayem*, 873 F.3d at 1324). At least, the contrary conclusion is not so clearly wrong as to justify canceling the jury's verdict.

Because the plaintiff's injury was not so distinct from "conditions naturally to be expected from her post-surgical condition," the timeliness of her claim was a fact question. *Eghnayem*, 873 F.3d at 1324. Thus, the district court properly denied Coloplast's motion.

3. Ms. Redding's cryptic testimony does not mandate judgment as a matter of law on the discovery rule issue.

This Court should not determine the discovery rule issue as a matter of law based on unclear testimony from Ms. Redding, during which she twice used the phrase: "I don't know." Coloplast's argument puts excessive weight on one two-letter pronoun: "it."

Coloplast contends that Ms. Redding knew, or should have known, that she had a claim against Coloplast based on this exchange during trial:

> Q. At that time [Dec. 28, 2009], did you believe that the products that had been implanted in you were unsafe?

> A. I thought something was wrong with it, that something was just not – I don't know. Something was wrong and I – I don't know.

(Doc. 342, Trans. Vol. 5, at 43:16-20). Ms. Redding then clarified that she knew something was wrong but did not know what it was. (*Id.* at 44:6-8).

At that time, Ms. Redding had an asymptomatic "tiny erosion," plus discharge, drainage, and odor that may have indicated an infection. (P170; Doc. 353, Trans. Vol. 8, at 127:8-12, 125:18-21, 167:5-11). Before surgery, Dr. Weaver warned her that erosions and infections were potential side effects of the mesh implant surgery. (Doc. 353, Trans. Vol. 8, at 103:17-23). These side effects—if she had an infection—occurred less than two weeks after surgery. (P170). The discharge and drainage resolved by her next appointment, on January 13, 2010. (Doc. 353, Trans. Vol. 8, at 134:14-18). The "tiny erosion" never became symptomatic. (*Id.* at 127:8-12; 135:7-14; 136:14-23; 139:8-12; 140:22-141:7). Thus, Ms. Redding had every reason to believe she had suffered minor complications from surgery.

Again, Ms. Redding acknowledged that the medical records provided a better history than her own memory. (Doc. 342, Trans. Vol. 5, at 85:12-17). Plus, her testimony is subject to varying interpretations. Did she know something was wrong with the product? Did she mean there was something wrong with her body? The surgery? The overall situation? This scenario demonstrates why appellate courts defer to juries. *See Amegy Bank*, 619 F. App'x at 931 (giving

"particular deference to credibility determinations of a fact-finder who had the opportunity to see live testimony"). The jury saw Ms. Redding's mannerisms and speech patterns. The jury was best positioned to determine what she was trying to say when she was clearly confused—she twice said: "I don't know." (Doc. 353, Trans. Vol. 8, at 43:16-20). This Court cannot discern her intended meaning simply by finding the antecedent to the pronoun "it" on a transcript. Further, the jury was entitled to credit Ms. Redding's clarification that she did not know what was wrong. (*Id.* at 44:6-8). Her testimony presents a question of fact for the jury, and they decided that question. (Verdict Form, Redding App. Doc. 397). This Court should not undo that decision. *See Siegelman*, 640 F.3d at 1165 (granting deference to jury decisions based on witness testimony).

4. The discovery rule applies even under Coloplast's formulation of the law.

This Court should simply apply the test from *Eghnayem* and *Perryman* to determine application of the discovery rule. But even under Coloplast's proposed legal framework, there is a fact question.

Coloplast admits that a plaintiff is not on notice that a product caused her injury unless the injury is "distinct in some way from conditions naturally to be expected from the plaintiff's condition." (Aplt. Br. at 37 (quoting *Babush*, 589 So. 2d at 1381). However, citing additional Florida cases, Coloplast claims that this

rule does not apply to "diagnosed" cases, where a plaintiff "was *told* that a product (mesh) caused her injury." (*Id.* at 37-38).

None of the cited cases frame the rule in precisely this manner. *Carter v. Brown & Williamson Tobacco Corp.*, 778 So. 2d 932, 934 (Fla. 2000), involved latent disease, and the court ruled that statute of limitations **had not** run. *American Optical Corp. v. Spiewak*, 73 So. 3d 120, 127 (Fla. 2011), stated in dicta that before an asbestos statute was passed, asbestos injuries accrued when a physician diagnosed a patient with asbestos-related disease. *University of Miami v. Bogorff*, 583 So. 2d 1000, 1004 (Fla. 1991), held that the statute began to run due to "a dramatic change in Adam's condition" that could be connected to the product. This Court applied that formulation in *Eghnayem* and *Perryman*—ironically, an approach that Coloplast has contested. (Aplt. Br. at 30-31).

Regardless, if diagnosis of injury caused by the product triggers accrual, then Ms. Redding's claims did not accrue in 2009 or 2010. There was no diagnosis of mesh injury at that time. As laid out above, the "tiny erosion" was asymptomatic, and all other post-surgery symptoms quickly resolved and were unrelated to the mesh. A reasonable jury could find that Ms. Redding was not diagnosed with a mesh injury, given that Dr. Weaver did not diagnose an injury that he attributed to the mesh.

The jury, therefore, could reasonably find that Ms. Redding neither discovered, nor should have discovered, "the facts giving rise to the cause of action." Fla. Stat. § 95.031(2)(b).

For all of these reasons, this Court should affirm the judgment.

II. This Court should reject Coloplast's request to certify a question to the Florida Supreme Court because there is no substantial doubt on how to apply Florida law.

The Court should deny Coloplast's request to certify a question to the Florida Supreme Court because there is no substantial doubt as to how to apply the Florida statute of limitations to this case. This clarity—as evidenced by this Court's recent decisions in *Eghnayem* and *Perryman*, and the Court's policy of restraint when asked to certify a question—supports deciding the appeal.[7] Additionally, the Florida Supreme Court would not consider Coloplast's proposed certified question because it is not case determinative.

A. Legal standard

Certifying a question to a state supreme court rests in this Court's "sound discretion." *Lehman Bros. v. Schein*, 416 U.S. 386, 390–91 (1974). This Court may certify a question if it "maintain[s] more than substantial doubt as to how the issue

[7] The parties also have a right to have their lawsuit decided without unnecessary delay. *Clay v. Sun Ins. Office Ltd.*, 363 U.S. 207, 224 (1960) (Black, J., dissenting).

before us would be resolved" under state law. *See Toomey v. Wachovia Ins. Servs., Inc.*, 450 F.3d 1225, 1231 (11th Cir. 2006). This Court shows "restraint" when it comes to certifying questions, even if there is some "doubt as to how the state court would resolve this issue." *City of Rome v. Hotels.com, L.P.*, 549 F. App'x 896, 904 (11th Cir. 2013); *Escareno v. Noltina Crucible & Refractory Corp.*, 139 F.3d 1456, 1461 (11th Cir. 1998), *certified question answered sub nom. Escareno v. Carl Nolte Sohne GmbH*, 270 Ga. 264, 507 S.E.2d 743 (1998) ("We sometimes will decide a question of state law, even when there is doubt as to how a state court would resolve the issue.")

The most important factors are the "closeness of the question and the existence of sufficient sources of state law … to allow a principled rather than conjectural conclusion." *State of Florida ex rel. Shevin v. Exxon Corp.*, 526 F.2d 266, 274 (5th Cir. 1976); *Escareno*, 139 F.3d at 1461 (applying *Shevin*). The court also should consider factors such as comity and practical limitations, including delay. *Id.*

B. This Court's decision in *Eghnayem* shows that there is no "substantial doubt" on how to apply Florida's statute of limitations, and that sufficient state law sources exist.

As shown by *Eghnayem*, there is no doubt—much less a substantial doubt—on how the Florida courts would apply the statute of limitations because there is sufficient Florida precedent. No certified question is necessary.

First, *Eghnayem*'s existence is sufficient to deny Coloplast's request to certify a question. As discussed above, *Eghnayem* applied the Florida statute of limitations to a case involving a defective mesh implant—the exact situation present here. *Eghnayem*, 873 F.3d at 1323-24. *Perryman* then applied *Eghnayem* to another mesh case addressing the Florida statute of limitations, meaning this Court has addressed the issue twice. *Perryman*, 748 F. App'x at 215-17.

Similarly, in *Restaurant Group Management*, *LLC v. Zurich Am. Ins. Co.*, No. 21-12107, 2022 WL 1931094 (11th Cir. June 6, 2022), this Court resolved an appeal based on its recent decision addressing the same question. *Id.* at *2. After reaffirming the need for "substantial doubt" and "judgment, restraint, and discretion" in certifying a question, the Court denied the motion to certify because "[i]n light of our binding decision in *Henry's Louisiana Grill*, we do not harbor substantial doubt about the correctness of the district court's decision here." *Id.* at *2 n.3. This Court should similarly deny Coloplast's request for certification because of *Eghnayem* and *Perryman*.

But even setting aside the above, *Eghnayem*'s analysis of Florida law, and the certainty with which it applies Florida law, show that no certified question is necessary.

In *Eghnayem*, pelvic mesh manufacturer Boston Scientific Corp. ("BSC") appealed a final judgment in the plaintiff's favor arguing, *inter alia*, that Florida's

statute of limitations barred her claims as a matter of law. *Eghnayem*, 873 F.3d at 1311. The jury rejected BSC's statute of limitations defense, and the district court denied BSC's motion for judgment notwithstanding the verdict. *Id.* at 1312-13.

This Court held that "[i]t was not unreasonable for the jury to find that Eghnayem' s claims accrued after … the cut-off point for the state's four-year statute of limitations." *Id.* at 1323. This Court reviewed Florida appellate decisions that "shed[] considerable light on what it takes for an injury to meet [Florida's] notice standard."

This Court also laid out how Florida courts have interpreted notice that starts the statute of limitations clock in similar circumstances:

- The notice need "not rise to that of legal certainty," but plaintiffs must have notice "of the possible invasion of their legal rights." *Id.* (citing *Bogorff*, 583 So. 2d at 1004);
- Notice "ha[s] two essential ingredients: an injury distinct in some way from conditions naturally to be expected from the plaintiff's condition, and … exposure to the product in question"; the "[u]se of the conjunction 'and' in this equation necessarily implies that the connection must be to some extent causal." *Id.* (citing *Babush*, 589 So. 2d at 1381).

- "[A]n injury must stand out from the norm to start the statutory clock." *Id.* at 1324 (citing *Norsworthy v. Holmes Reg'l Med. Ctr., Inc.*, 598 So. 2d 105, 107-08 (Fla. Dist. Ct. App. 1992) (case from the "highly analogous medical malpractice context").

This Court looked at how the Florida appellate courts applied the notice requirement to similar facts:

- "[T]he Florida Supreme Court concluded that a three-year-old's symptoms of slurred speech, impaired motor skills, convulsions, coma, and resultant paralysis and brain damage, which coincided in time with the introduction of a particular leukemia medication, were sufficiently dramatic to provide notice to his parents." *Id.* (citing *Bogorff*, 583 So. 2d at 1001, 1004).
- "[A] Florida appellate court held … that a child's difficulty breathing following an invasive medical procedure was not so obviously unusual that it put his parents on notice of their

malpractice claim." *Id.* at 1323-24 (citing *Norsworthy*, 598 So. 2d at 108).[8]

This Court then affirmed the verdict because it was not "clear that Eghnayem was aware of a 'dramatic change in [her] condition,' and further that she knew of the possible involvement of the [mesh device] in that change … four years before she filed suit." *Id.* at 1324.

Nowhere did this Court suggest doubt about how to apply Florida law, or that it lacked Florida sources, necessitating an *Erie* guess. *See generally id.* The *Perryman* decision emphasizes this point. In *Perryman*, this Court held that it "must apply the standard used in *Eghnayem*" when reviewing whether the statute of limitations had run. This Court then summarized *Eghnayem*'s analysis and held that it dictated the same result. *Perryman*, 748 F. App'x at 217. The application of *Eghnayem* and Florida law was so settled that it did not even warrant publishing the decision.

Many subsequent cases have likewise agreed with and applied *Eghnayem*'s holding.[9] *Boneta*, 524 F. Supp. 3d at 1314–17; *Pirlein v. Ethicon, Inc.*, No. 20-

[8] To the extent that Coloplast argues that the medical malpractice field does not provide an analogue for notice under the statute of limitations, its brief belies its argument. (*See* Aplt. Br. at 37 (including "[e]xamples from medical malpractice cases" to support argument)).

[9] Coloplast cites *Sotolongo v. Ethicon, Inc.*, 591 F. Supp. 3d 1242 (S.D. Fla. 2022), to suggest that the district courts disagree on how to apply Florida law. But *Sotolongo* stands alone because the district court held that the statute of limitations

62202-CIV, 2021 WL 4990612, at *5 (S.D. Fla. Oct. 1, 2021); *Kresch v. Miller*, No. CV 18-10025, 2021 WL 253974, at *6 (E.D. Mich. Jan. 26, 2021) (applying Eghnayem to a fraud claim under Florida law); *Mason v. Ethicon, Inc.*, No. 620CV1078ORL37DCI, 2020 WL 6270847, at *2 (M.D. Fla. Sept. 9, 2020); *Crespo v. Merck & Co.*, No. 12MD2331BMCPK, 2020 WL 5369045, at *3-4 (E.D.N.Y. Sept. 8, 2020) (applying Florida law); *Ellerbee v. Ethicon, Inc.*, No. 8:20-CV-1514-T-60AEP, 2020 WL 5230595, at *2 (M.D. Fla. Sept. 2, 2020).

There is no substantial doubt about how to apply Florida's statute of limitations to this case. The Court should deny Coloplast's request for a certified question.

C. Coloplast's arguments that a certified question is necessary are flawed.

Coloplast's other arguments for certification are flawed. First, Coloplast creates a three part test from the introductory paragraph in *In re Cassell*, 688 F.3d 1291, 1292 (11th Cir. 2012), *certified question answered sub nom. Silliman v. Cassell*, 292 Ga. 464, 738 S.E.2d 606 (2013). (Aplt. Br. at 39). But Coloplast ignores that the case focused on the need to have "a substantial doubt about the correct answer to a dispositive question of state law." *See In re Cassell*, 688 F.3d at

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had run as a matter of law but failed to consider any of the recent precedent from this Court, including *Eghnayem* and *Perryman*. *See generally id.* The plaintiff appealed, and then the parties settled the case.

1292, 1300-01. So, while "unsettled," "important," and "recurring" are considerations, the main question is whether there are enough Florida sources for this Court to avoid guessing. *See Mosher v. Speedstar Div. of AMCA Int'l, Inc.*, 52 F.3d 913, 916–17 (11th Cir. 1995) (courts should only certify "truly debatable questions" to avoid "unnecessary Erie guesses"); *see also Pendergast v. Sprint Nextel Corp.*, 592 F.3d 1119, 1143 (11th Cir. 2010); *State of Florida ex rel. Shevin v. Exxon Corp.*, 526 F.2d 266, 274 (5th Cir. 1976);

Second, federalism and comity do not support a certified question merely because the Florida Supreme Court has not "weighed in" on a pelvic mesh case. Requiring the Supreme Court to apply the statute of limitations first for every product that encounters litigation "would undermine the purposes of diversity jurisdiction, cause undue delay in resolving disputes, and burden the state courts with cases that we can readily resolve." *Smith v. Cont'l Cas. Co.*, No. 20-3004, 2021 WL 4523706, at *14 (6th Cir. Oct. 4, 2021); *see also Howard v. Kimley-Horn & Assocs., Inc.*, No. 21-11099, 2021 WL 4452536, at *5 (11th Cir. Sept. 29, 2021) (holding that Georgia law was sufficiently settled based on Court of Appeals decisions, even in the absence of a Supreme Court decision).

Third, Coloplast is incorrect in claiming that the district court's application of *Eghnayem* is a "departure" from Florida precedent. Coloplast inaccurately asserts that the district court held that "knowledge of a product defect is required to

start the limitations period." The district court did not use that language. Instead, it held that there was insufficient evidence to hold, as a matter of law, that the limitations period had run, leaving the issue for the jury. (Doc. 405 at 7). The court did not depart from Florida law. Rather, the court applied Florida's requirement that there be a causal connection between the injury and the product before the cause of action accrues. (*See id.*).

And, far from casting doubt, *Carter* emphasized that a product liability action accrues "'only when the accumulated effects of the deleterious substance manifest themselves [to the claimant],' in a way which supplies some evidence of causal relationship to the manufactured product." *Carter*, 778 So. 2d at 936. *See also Boneta*, 524 F. Supp. 3d at 1314 (stating that in *Carter* "[t]he Florida Supreme Court thus moved away from the rule cited by Defendant and brought the notice standard applied to medical malpractice actions in line with the standard applied to products liability claims").

Neither *Eghnayem* nor the district court's application of it departed from Florida precedent. This Court, therefore, should find that nothing warrants certifying a question to the Florida Supreme Court. Doing so would unnecessarily delay this case's resolution.

D. The Florida Supreme Court could not take Coloplast's proposed question because it is not case determinative.

Another reason not to certify a question to Florida Supreme Court is that the court could not take it. If a question of law is "determinative of the cause" and "no controlling precedent" from the Florida Supreme Court exists, then the Florida Supreme Court may accept a certified question. Fla. Const. art V, § 3(b)(6). The Florida Supreme Court could not take Coloplast's question because it is not case determinative. [10]

The proposed certified question asks:

> In a product-liability lawsuit alleging that a defectively designed mesh device eroded and thereby caused pelvic pain, does Florida Statute § 95.031(2)(b) begin to accrue as a matter of law when the plaintiff is diagnosed with an erosion of the mesh causing pelvic pain, and the plaintiff also knows that "something was wrong" with the mesh device?

(Aplt. Br. at 38).

Not only does Coloplast pose a largely factual question, but it also imposes Coloplast's (inaccurate) view of the evidence. Dr. Weaver did not diagnose Ms. Redding with "an erosion of the mesh causing pelvic pain." He observed an **asymptomatic** "tiny erosion." (P170; Doc. 353, Trans. Vol. 8, at 126:11-127:7) (no pain documented in medical records and Dr. Weaver would have documented

[10] While this Court could hypothetically reframe the question, it should decline to do so when the question does not even present a purely legal issue.

pain if it had occurred); P175; Doc. 342, Trans. Vol. 5, at 139:18-20 (Ms. Redding was "doing well" on her last visit with Dr. Weaver)). As discussed above, Ms. Redding testified that she knew something was wrong, but she did not know what it was. (*Id.* at 44:6-8). The Jury answered "No" when the verdict form specifically asked if "the Plaintiff knew, or by the use of reasonable care should have known, on or before September 18, 2010, that she had been injured or damaged and that there was a reasonable possibility that the injury or damages was caused by a defect in the Defendant's product." (Verdict Form, Redding App., Doc. 397).

Even if some evidence supports Coloplast's view, there is ample evidence to support the jury's finding that the statute of limitations had not run, as laid out above, and therefore the jury's fact-finding should stand. *See Eghnayem*, 873 F.3d at 1313 ("Thus, we've explained, '[j]udgment as a matter of law is appropriate only if the evidence is so overwhelmingly in favor of the moving party that a reasonable jury could not arrive at a contrary verdict.'") (citing *Middlebrooks*, 256 F.3d at 1246).

The case's outcome would be the same regardless of how the Florida Supreme Court answered Coloplast's proposed certified question, because the question does not present the facts of this case. It does not matter how the Florida Supreme Court would decide a case where the plaintiff is diagnosed with a mesh erosion that caused pelvic pain, as that is not this case (during the relevant

period).[11] This Court should deny Coloplast's motion to certify a question on the statute of limitations. It is not "determinative of the cause," as is required for the Florida Supreme Court to take it. Fla. Const. art. V, § 3.[12]

CONCLUSION

For the reasons stated above, this Court should affirm the district court's denial of Coloplast's motion for judgment notwithstanding the verdict. The evidence strongly supports the jury's verdict. Ms. Redding did not suffer any compensable injury in 2009 or 2010, so the statute of limitations could not have begun running. Further, a reasonable jury could conclude that she did not know, nor should she have known, that she had a claim against Coloplast before September 2010. Finally, this Court should not certify the question to the Florida Supreme Court, as the law is settled, the facts support the verdict, and the proposed question is immaterial.

[11] A related reason that the Florida Supreme Court would reject certification is that it cannot issue advisory opinions. *See, e.g.*, *Est. of McCall v. United States*, 134 So. 3d 894, 915 (Fla. 2014) (with limited exceptions, the Florida Supreme Court may not give advisory opinions). Because the certified question does not present the facts of this case, any opinion answering that question would be advisory.

[12] This Court's precedent also notes that it should only certify questions when they are dispositive. *In re Cassell*, 688 F.3d at 1300 (certification may be appropriate "when there is substantial doubt about the correct answer to a dispositive question of state law").

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed this brief on March 30, 2023, using the Court's EFC filing system, thereby sending notice of the filing to all counsel of record.

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CERTIFICATE OF COMPLIANCE

I hereby certify that I this brief complies with the type-volume requirement of Fed. R. App. P. 32(a)(7)(B)(i) because it is a principal brief and contains 12,119 words, as measured by the word processing system used to create the brief.

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